

NOV 09 2001

8. SUMMARY OF 510(k) SAFETY AND EFFECTIVENESS

This summary of safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

The Assigned 510(k) number is K012824.

Submitter:

ACON Laboratories, Inc.
4108 Sorrento Valley Boulevard
San Diego, California 92121

Tel.: 858-535-2030

Fax: 858-535-2038

Date:

August 17, 2001

Contact Person:

Edward Tung, Ph.D.

Product Names:

ACON® BAR One Step Barbiturates Test Strip

ACON® BAR One Step Barbiturates Test Device

Common Name:

Immunochromatographic test for the qualitative detection of barbiturates in urine

Device Classification:

The ACON BAR One Step Barbiturates Test Strip and ACON BAR One Step Barbiturates Test Device are similar to other FDA-cleared devices for the qualitative detection of barbiturates in urine specimens. These tests are used to provide a preliminary analytical result (21 CFR 862.3150). This type of barbiturates test systems (Product Code: DIS) have been classified as Class II devices with moderate complexity.

Classification Name:

Barbiturates test system

Intended Use:

The ACON® BAR One Step Barbiturates Test Strip and ACON BAR One Step Barbiturates Test Device are rapid chromatographic immunoassays for the qualitative detection of barbiturates in urine at a cut-off concentration of 300 ng/mL. They are intended for use by healthcare professionals including professionals at point-of-care sites.

Description:

The ACON BAR One Step Barbiturates Test Strip and ACON BAR One Step Barbiturates Test Device are competitive binding, lateral flow immunochromatographic assays for the qualitative screening of barbiturates in a urine sample. The test is based on the principle of antigen-antibody immunochemistry. It utilizes the antibody to selectively detect elevated levels of barbiturates in urine specimens at a designated cut-off concentration of 300 ng/mL. These tests can be performed without the use of an instrument.

A drug-positive urine specimen will not generate a colored-line in the designated test region, while a negative urine specimen or a urine specimen containing barbiturates at the concentration below the cut-off level will generate a colored-line in the test region. To serve as a procedural control, a colored-line will always appear at the control region, indicating that proper volume of specimen has been added and membrane wicking has occurred.

Predicate Device:

MCC Instant Screen Card BAR Test

Distributed by Medical & Clinical Consortium
(MCC), City of Industry, CA 91746-2048

510(k) Number: K002337

Comparison to a Predicate Device:

A comparison of the features of the ACON BAR One Step Barbiturates Test Strip and ACON BAR One Step Barbiturates Test Device versus the MCC Instant Screen Card BAR Test is shown below:

- Both tests are assays intended for the qualitative detection of barbiturates in urine samples.
- Both tests are intended as a screening method that provides a preliminary analytical test result.
- Both tests are immunochromatographic, lateral flow assays for the rapid detection of barbiturates with a visual, qualitative end result.
- Both tests utilize the same basic immunoassay principles that rely on antigen/antibody interactions to indicate a positive or negative result.
- Both tests have a cut-off concentration of 300 ng/mL for secobarbital.

Safety and Effectiveness Data:

Accuracy

A clinical evaluation was conducted using 292 clinical urine specimens including 10% of the samples with barbiturate concentrations at -25% cut-off to +25% cut-off range. This evaluation compared the test results between ACON® BAR One Step Barbiturates Test Strip and Test Device with MCC Instant Screen Card BAR Test; as well as against data obtained from the customary Gas Chromatography/Mass Spectrometry analysis. The comparisons of data obtained from this study yielded the following results:

ACON BAR One Step Barbiturates Test Strip versus MCC Instant Screen Card BAR Test:

Positive Agreement: $126 / 126 = 100\%$ (97% -100%*)
 Negative Agreement: $165 / 166 = 99\%$ (97% -100%*)
 Overall Agreement: $291 / 292 = 99\%$ (98 % -100%*)

* 95% Confidence Intervals

ACON BAR One Step Barbiturates Test Device versus the MCC Instant Screen Card BAR Test:

Positive Agreement: $126 / 126 = 100\%$ (97% -100%*)
 Negative Agreement: $165 / 166 = 99\%$ (97% -100%*)
 Overall Agreement: $291 / 292 = 99\%$ (98 % -100%*)

* 95% Confidence Intervals

ACON BAR One Step Barbiturates Test Strip versus GC/MS at the secobarbital cut-off concentration of 300 ng/ml:

Positive agreement with GC/MS: $122 / 132 = 92\%$ (86% -96%*)
 Negative agreement with GC/MS: $156 / 160 = 98\%$ (94% -99%*)
 Total agreement with GC/MS: $278 / 292 = 95\%$ (92% -97%*)

* 95% confidence intervals

ACON BAR One-Step Barbiturates Test Device versus GC/MS at the secobarbital cut-off concentration of 300 ng/ml:

Positive agreement with GC/MS: 122 / 132 = 92% (86% -96%*)

Negative agreement with GC/MS: 156 / 160 = 98% (94% -99%*)

Total agreement with GC/MS: 278 / 292 = 95% (92% -97%*)

* 95% confidence intervals

Conclusion:

These clinical studies demonstrate the substantial equivalency between the ACON BAR One Step Barbiturates Test Strip, ACON BAR One Step Barbiturates Test Device and the MCC Instant Screen Card BAR Test, which has already being marketed in the United States. It is also demonstrated in the performance studies that the ACON BAR One Step Barbiturates Test Strip, ACON BAR One Step Barbiturates Test Device are safe and effective in qualitatively detecting barbiturates in urine specimens at a secobarbital cut-off concentration of 300 ng/mL. The POL study demonstrated that these tests are suitable for use by healthcare professionals including professionals at point-of-care sites.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

NOV 09 2001

Edward Tung, Ph.D.
Director of Regulatory Affairs
ACON Laboratories, Inc.
4108 Sorrento Valley BLvd.
San Diego, CA 92121

Re: k012824
Trade/Device Name: ACON® BAR One Step Barbiturates Test Strip and
ACON® BAR One Step Barbiturates Test Strip Device
Regulation Number: 21 CFR 862.3150
Regulation Name: Barbiturate test system
Regulatory Class: Class II
Product Code: DIS
Dated: August 21, 2001
Received: August 23, 2001

Dear Dr. Tung:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

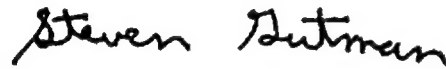
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4588. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "<http://www.fda.gov/cdrh/dsma/dsmamain.html>".

Sincerely yours,

A handwritten signature in black ink that reads "Steven Gutman". The signature is written in a cursive, slightly slanted style.

Steven I. Gutman, M.D., M.B.A.
Director
Division of Clinical Laboratory-Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

10. INDICATIONS FOR USE

NOV 09 2001

510(k) Number: K012824

Device Name: ACON® BAR One Step Barbiturates Test Strip

ACON® BAR One Step Barbiturates Test Device

Indications for Use:

The ACON BAR One Step Barbiturates Test Strip and ACON BAR One Step Barbiturates Test Device are rapid chromatographic immunoassays for the qualitative detection of barbiturates in human urine at a level relative to the secobarbital cut-off concentration of 300 ng/mL. They are intended for use by healthcare professionals including professionals at point of care sites.

Steve A. Chandler for Jean Cooper

(Division Sign-Off)

Division of Clinical Laboratory Devices

510(k) Number _____

(Please do not write below this point)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓

Or

Over-The-Counter Use _____

(Per 21 CFR 801.109)